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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/911,423	08/14/97	GORMAN	DX0612K1

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EXAMINER
TUNG, M

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 09/14/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action SummaryApplication No.
08/911,423Applicant(s)
Gorman, et al.Examiner
Mary TungGroup Art Unit
1644☒ Responsive to communication(s) filed on 7/10/98☐ This action is **FINAL**.☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims☒ Claim(s) 1-22 is/are pending in the application.Of the above, claim(s) 1-8, 13-16, 21, and 22 is/are withdrawn from consideration.☐ Claim(s) _____ is/are allowed.☒ Claim(s) 9-12 and 17-20 is/are rejected.☐ Claim(s) _____ is/are objected to.☐ Claims _____ are subject to restriction or election requirement.**Application Papers**☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.☐ The drawing(s) filed on _____ is/are objected to by the Examiner.☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.☐ The specification is objected to by the Examiner.☐ The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119**☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.☐ received in Application No. (Series Code/Serial Number) _____.☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)**☒ Notice of References Cited, PTO-892☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4 and 5☐ Interview Summary, PTO-413☐ Notice of Draftsperson's Patent Drawing Review, PTO-948☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group IV, claims 9-12, 17, 19 and 20 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the claims are so closely related that they should remain in the same application to preserve unity of invention. Additionally, the applicant argues that "there is considerable overlap in search." This is not found persuasive because "unity of invention" is applied only in national cases filed under 35 U.S.C. 371 and not in non-international U.S. applications (*see MPEP § 1850*). The instant application was filed under 35 U.S.C. 111 and thus, restriction practice under 35 U.S.C. 121 (*see MPEP § 802*). Additionally, as the applicants have pointed out, "restriction must be based upon their distinctness, as claimed." The Examiner has discussed in the Office Action mailed May 11, 1998, that Groups I, II, IV, V and VIII are unique products. They differ with respect to their physicochemical properties and are therefore patentably distinct. Additionally, Groups III, VI, VII and IX are unique methods. They differ with respect to ingredients and method steps. The method of purifying the 312C2 protein of Group III would not suggest the method for detecting 312C2 in a sample as recited in Group VI. Nor would the methods of Groups III and VI suggest the treatment of cells or mammals as recited in Groups VII or IX, respectively. Additionally, a method of treating a cell in Group VII would involve different steps, reagents and materials than a treatment of a mammal in Group IX. They are therefore, patentably distinct each from the other.
2. Because a search of any of these distinct inventions would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious undue burden on the Examiner.
3. The requirement is still deemed proper and is therefore made FINAL.
4. Groups I-III and V-VIII, claims 1-8, 13-16, 21 and 22 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions, the requirement having been traversed in Paper No. 8. Upon reconsideration, the cell comprising a nucleic acid, recited in claim 18, will be examined along with the elected invention. The embodiment of claim 12 which encompasses the nucleic acid encoding the 312C2 peptide was examined along with the elected invention. The other embodiments recited in claim 12 are withdrawn by the Examiner as being drawn to non-elected inventions of Groups I and II, as set forth in the Office Action mailed May 11, 1998.
5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Specification

6. The use of trademarks such as "PHOTOPROBE," page 56, line 32, of the specification has been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the propriety nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

7. Each letter of the trademarks must be capitalized. *See MPEP 608.01(V) and Appendix I.*

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 9-12, 17-20 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claims 9-12 and 17-20 are incomplete because they depend upon claim 1, which was not elected.

11. Claims 9-12 and 17-20 recite the designation "312C2". The amino acid sequence and the nucleic acid encoding said sequence must be identified by SEQ ID NO.

12. Claim 10 recites sections a-g. It is unclear whether sections a-d and e-f, constitute separate Markush groups, or if a-c and d-g constitute Markush groups. The Examiner assumed the groups as a-d and e-f, for the purposes of examination.

13. Claim 11 recites the limitation "vector of claim 9." There is insufficient antecedent basis for this limitation in the claim.

14. Claim 17 recites the phrase "expressing a nucleic acid". It is unclear what the applicant intends to be encompassed by this claim, the protein expressed by the nucleic acid or duplicate copies of the nucleic acid.

15. Claims 19 and 20 recite the phrase "at least about". This phrase renders the claim indefinite because the degree of deviation from the recited percent identity is unclear.
16. Claims 19 and 20 are indefinite in the recitation of "% identity". The use of such terms as percent homology, percent similarity, and percent identity in connection with a recited amino acid or nucleic acid sequence is vague and indefinite in the absence of a clear description or definition of what the term means. This is because sequence identity between two sequences has no common meaning within the art. Although the methods for determining identity between two sequences, such as the use of programs like CLUSTAL, GAP, BLAST, or FASTA, as disclosed on page 9, lines 32-37 of the specification, does not adequately describe how the applicants themselves determined the percent identity. The disclosure does not allow one skilled in the art to determine the existence of gaps, or which mismatches, alterations or mutations are encompassed by the claims. It is therefore unclear what isolated sequences the applicants claim.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Matoba (U) or Matoba, et al. (GenBank, Accession #D17247 (V)).
19. Matoba (V) teaches an isolated purified polynucleotide sequence 98 bp in length with a sequence identity of 79.6% over its entire length with SEQ ID NO: 3, using the MPSEARCH program, with gaps set at '6'. The reference teachings thus anticipate the claimed invention.
20. Claim 19 is rejected under 35 U.S.C. 102(a) as being anticipated by Goldstein (WO 96/15272).
21. The '272 patent teaches an isolated purified polynucleotide sequence 52 bp in length with a sequence identity of 96.3% (SEQ ID NO: 73) over its entire length with SEQ ID NO: 3 of the instant application, using the MPSEARCH program, with gaps set at '6'. The reference teachings thus anticipate the claimed invention.

Conclusion

22. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.
26. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). THE CM1 FAX CENTER TELEPHONE NUMBER IS (703) 305-3014 or (703) 308-4242.
26. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Mary Tung whose telephone number is (703)308-9344. The Examiner can normally be reached Monday through Friday from 8:30 am to 5:30 pm. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1640 receptionist whose telephone number is (703) 308-0196.

Mary B Tung
September 12, 1998
Mary B/ Tung, Ph.D.
Patent Examiner
Group 1640

Christina Chan
CHRISTINA Y. CHAN
SUPERVISORY PATENT EXAMINER
GROUP-1800-1640